S. Sebastian
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DRUGS CONTROL DEPARTMENT

KARNATAKA

REQUIREMENTS OF BLOOD BANKS

AND

CAUSES AND PREVENTION OF AIDS

Meeting Held on 6th August, 1988

0511

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SECTION - I

SECTION - I

BLOOD BANK - REQUIREMENTS

(as per Drugs & Cosmetic Rules 1945) Page 1-9.)

DONOR SELECTION

Whole human blood is blood which has been mixed with a suitable anticoagulant.

The Donor selection shall be made by the Physician. The following minimum requirements shall be observed :

a) The blood donor shall not be less than 18 years of age.

b) No blood donor shall have more than 400ml of blood withdrawn from him as a blood donation on any one occasion and the interval between any two consecutive blood donations from any one donor shall be not less than 12 weeks, unless the blood is drawn by the process of plasmaphersis.

c) On the day of the intended blood donation, the following procedure shall be carried out :-

i) Identification and registration of the donor.

ii) Assessment of the physical fitness of the donor for giving a blood donation by the Physician who shall base his opinion upon the donor's medical history and upon such clinical examination and tests that are considered essential to fulfil the minimum requirements for enrolling blood donor (Those giving a history of viral hepatitis during the last 5 years,syphilis, tuberculosis should not be accepted).

iii) Determination of haemoglobin levels of the donor.

Human blood meant for transfusion should not be obtained from a human subject ,

a) Whose blood is tested for positive results for evidence for syphilitic infection, or

b) Who is known to be suffering from or have suffered from syphilis, or

c) The haemoglobin value of whose blood is less than 85 percent, (12.5 gms. per 100ml), or

d) Who is not as far as can be ascertained by a qualified Physician after inspection or simple clinical examination and consideration of his medical history free from disease transmisable by blood transfusion (Ex: Tuberculosis, etc.).

e) Who has positive results for the presence of Anstralia, Antigen and Antibodies. This test is to eliminate any risk of occurence of Jaundice as a result of blood transfusion (Ex: Viral hepatitis).

f) Who has any symptoms of AIDS virus.

Preparation

The whole blood is withdrawn aseptically through a closed system of sterile tubing into a sterile container in which the anticoagulant solution has been placed before the container is sterilised.

After the withdrawal is complete, the container is immediately sealed and cooled to 4°C - 6°C and thereafter opened only,

(a) for the purpose of withdrawing a sample of blood for direct matching with the recipient 's serum and

(b) when the blood is administered.

The blood is collected into a citrate solution of acid reaction containing dextrose.

Registers to be maintained should contain

1. Blood Donor details
2. Analytical details
3. Distribution details

EQUIPMENT AND SUPPLIES REQUIRED FOR A BLOOD BANK

BLOOD DONOR ROOM

(A) **Equipment :**

The blood donor room shall be airconditioned.

1. Donor beds or tables: The top of the bed or the table shall be padded with heavy felt or foam rubber and shall be covered with a washable plastic material. The top of the bed or the table shall be sufficiently wide to give support to the arm of the donor. The table shall also be suitable to the requirements besides being comfortable.

2. Bed side stand.

3. Shaking apparatus or apparatus for mixing blood by technical staff.

4. Sphygmomnometer and stethoscope.

5. Recovery bed of about 40 cm. in height.

6. Accessory items : Such as blankets, emesis basins, hemostats, donor set clamps, sponge, forceps, dressing jars, solution jars, waste cans and adjustable lamps.

(B) **Blood Collection Supplies**

The blood collection shall be done either by the closed method or by the gravity method. Donor sets with 16 S.W.G. 5 C.m needles, donor bottles (Pyrogen free), lancets for haemoglobin and pilot tubes shall be sterile and ready for being used. The needles shall be piercing needles and made of stainless steel gauge 11 X 16 cm or 26 cm length depending upon the size of the bottle. When the gravity method is used, the outlet needles must have a sterile cotton wool filter.

1. **Haemoglobin Determination**

(a) Copper Sulphate solution, specific gravity, 1.052

(b) Sterile Lancets.

(c) Capillary tubing 1.3 - 1.4 X 65 mm or Pasteur Pippettes.

(d) Rubber bulbs for capillary tubings.

(e) Sahli's Haemoglobinometer.

2. Temperature and Pulse determination

(a) Clinical Thermometers

(b) Equipment and material for aseptic cleaning the thermometer.

(c) Watch (fitted with a seconds hand needle).

3. Blood collection bottles - 375 ml

4. Blood collection sets

5. Sterile pilot tubes for being attached to the flow bottle.

6. Hypodermic syringes 2ml needle of 26% S.W.G. / 1.5 cm

7. Cotton gauze squares (5cm x 5 cm), medium cotton balls, 1.25cm adhesive tape.

8. Alcohol (70%), green soap or liquid soap; Tincture Iodine and Injection of Procaine or Hexachlorophene liquid.

9. Paper napkins or towels.

(C) **Canteen equipment**

Provision for serving refreshments to the donor after phlebotomy may also be made so that he may be kept for observation in the Blood Bank for any reactions.

(D) **Emergency equipment**

1. Small Oxygen cylinder with mask, gauge and pressure regulator.

2. Plasma and / or Albumin (Human).

3. Sterile syringe and needle.

4. Sterile I.V. Infusion set.

5. Ampoules of Adrenaline, Injection of Calcium Gluconate, Injection of Atropine, Injection of Nikethamide and Injection of Non-adrenaline, Distilled Water.

6. Aspirin and Aromatic water.

LABORATORY

(A) Equipment

1. Refrigerators maintaining a temperature between 4°C to 6°C, with as little deviation as possible in temperature.

2. Alarm system for alerting a person on duty in event of very high deviation in temperature or failure of the machine.

3. Recording thermometer for refrigerator.

4. Charts and ink for recording thermometer.

5. Microscope, compound with low and high power objectives.

6. Centrifuges - Table model for blood grouping and cross matching.

7. Water baths one for 37° C and another for 56°C.

8. Rh viewing box. The surface of viewing glass shall not have "hot-spots", its temperature shall not exceed 47° C.

9. Incubator, bacteriological for control cultures. .

10. Mechanical shakers for serological tests for syphilis.

11. Hand lens for observing tests conducted in tubes.

12. Pipettes, serological, 1.0 ml, graduated in .001, .01, 0.2 ml.

13. Pipettes, Pasteur.

14. Glass slides, glass plates and / or porcelain deep wells or plates.

15. Test tubes, serological, 13 x 100 mm.

16. Test Tube racks.

17. Precipiting tubes 6mm x 50 mm

18. 15 cm applicators and toothpicks.

19. Interval timer, electric or spring wound.

20. Equipment and material for cleaning glassware adequately.

21. Shipping containers.

(B) **Reagents**

1. Standard Blood grouping Sera, Anti-A and Anti-B and Anti-AB, all in double quantity and each of a different brand , or if from the same suppliers each supply should be of a different lot number.

2. Rh typing sera. All in double quantity and each of a different brand or if from the same supplier, each supply should be of a different lot number.

3. Reagents for serological tests for syphilis and positive sera for controls.

4. Anti-human globulin serum (Coombs serum) for confirming cross-matches, determining Rh negative blood and performing antibody tests.

5. Albumin, human or bovine, 30% for tests, requiring high protein concentration.

6. 0.9% saline

7. Culture media tubes

8. Wax pencils and Labels.

9. Detergents and other agents for cleaning laboratory glassware.

GENERAL SUPPLIES

1. Autoclave

2. Temperature recorder (The autoclave should be equipped with a temperature recording device, which gives a record of temperature and length of time for each sterilisation).

TECHNICAL STAFF

1. A medical graduate having experience in Blood Bank
2. Registered Nurse - One.
3. Blood Bank technician having experience in blood grouping and serology work.
4. One Assistant
5. One Attendant.

ACCOMMODATION FOR BLOOD BANK

Minimum total area should be about 100 square metres and consisting of six rooms namely :

1. Registration and medical examination room
2. Blood Collection room
3. Room for laboratory
4. Room for sterlising and washing.
5. Refreshment room.
6. Room for keeping records and stores.

LABEL FOR WHOLE BLOOD

The label on the blood container should contain the following particulars namely :-

1. The serial number of the bottle.
2. The date on which the blood is drawn, and the date of expiry which shall not be more than 21 days from the date on which the blood is drawn.
3. The ABO group with the corresponding colour.

COLOUR SCHEME FOR LABELS

The following Colour Scheme for labels may be used for different groups :

Group	Colour of label
O	Blue
A	Yellow
B	Pink
AB	White

4. The Rh group

5. The total volume of fluid, the proportion of blood and the formula and proportion of anticoagulant.

6. The contents should not be used if there is any visible evidence of deterioration.

7. Name of Blood Bank

8. Address.

9. A filter must be used in administration equipment

10. Keep continuously at 4° to 6°C.

11. Cross-match before using.

Precautionary Measures

1. Administer without warming

2. Shake gently before using

3. Do not add other medication to the blood

4. Check blood group on label and recipient's group, before administration.

5. Use a fresh, clean and sterile transfusion set to transfuse the blood.

6. Do not dispense without prescription.

1. ETIOLOGY

A. What is AIDS ?

* AIDS , an acronym for Acquired Immunodeficiency Syndrome, is a serious clinical condition of various manifestations characterized by underlying cellular immunodeficiency.

* Because of this immune deficiency status, the patient is vulnerable to serious illnesses which would not be a threat to an individual whose immune system was functioning normally.

* The clinical manifestations of LAV/HTLV-III infection may be directly attributable to infection with the virus or the result of secondary conditions occuring as a consequence of immune dysfunction.

* AIDS is one manifestaion of infection with LAV/HTLV-III virus.

B. When was AIDS as a syndrome first identified?

* AIDS was first described in the USA in 1981.

* Retrospective studies indicate that the first U.S. cases may have occured as early as 1978.

C. What causes AIDS ?

* A newly recognized retrovirus has been shown to be the cause of AIDS.

* This retrovirus has been given several names, including lymphadenopathy-associated virus (LAV) and human T-lympho-tropic virus type III (HTLV-III). The exact title of the virus has not been finalised by the International Committee on Taxonomy of viruses.

* There are diseases in animals that share immunological and pathological characterstics with AIDS in man. The retro-viruses that cause these diseases, however, are not identical to the LAV / HTLV-III virus.

D. **When was the LAV / HTLV-III virus first identified ?**

* Scientists at the Pasteur Institute in Paris first described the AIDS virus (LAV) from a person with enlarged lymph nodes who was considered to be in a pre-AIDS state in May 1983; scientists at the U.S. National Cancer Institute published an extensive report on the virus (HTLV-III) in early 1984.

E. **How did the disease originate ?**

* Scientists are currently speculating on the origin of this virus. It appears evident that the virus was also occuring elsewhere in the world at the time it was first recognized in the USA and Western Europe.

F. **How does the virus work ?**

* The LAV / HTLV-III virus specifically infects and destroys the T-helper cells, a class of lymphocytes that plays a central role in orchestrating the body's defenses.

* T cells are thus unable to stimulate B cells, which normally multiply and produce antibodies that attack the invading virus.

* The virus essentially converts the T cell from a lymphocyte to an LAV / HTLV-III virus factory. Damaged T cells produce the virus which subsequently invades other T Cells.

* With an acquired immunodeficiency status, the AIDS victim is left vulnerable to an array of life-threatening infections and malignancies.

* Like other retroviruses, however, the result of LAV / HTLV-III infection may be variable. The virus may remain in a state of latency in the white blood cells or replicate without causing any symptoms/signs in the infected individual.

G. **What is the incubation period for AIDS ?**

* The period between infection with LAV / HTLV-III and the onset of AIDS symptoms seems to range from 6 months to 5 years, and possibly longer.

* Based on the information available to date, infection with this virus most often does not lead to AIDS during the first few years after infection. Study results thus far indicate that about two-thirds of those individuals infected with LAV/HTLV-III have developed no signs of illness within the first 5 years after infection. A proportion of the remaining one-third have developed a condition known as ARC or AIDS-Related Complex. ARC is characterized by chronic symptoms such as fatigue, low-grade fever, lymphadenopathy, diarrhoea and weight loss.

II. SIGNS / SYMPTOMS

A. Why is AIDS called a syndrome ?

* AIDS is referred to as a syndrome because the range of manifestations may include a variety of opportunistic infections, neurological disorders and several types of malignancies.

B. What are its symptoms ?

* Most individuals infected with the virus have no symptoms and feel well.

* Some develop symptoms which may include fatigue, fever, loss of appetite and weight, diarohoea, night sweats and swollen glands - usually in the neck, armpits or groin.

* Anyone with these symptoms which continue for more than two weeks should see a doctor.

* About 85% of the AIDS patients studied in the United States and Western Europe have had one or both of the two rare diseases:

  - **Pneumocystis carinii** pneumonia (PCP), a parasitic infection of the lung ;

  - Kaposi's sarcoma (KS), a cancer which usually occurs anywhere on the surface of the skin or in the mouth.

* Other opportunistic infections include unusually severe infections with yeast, cytomegalovirus, herpesvirus, and parasites such as **Toxoplasma** or **Cryptosporidia.**

* Milder infections with these organisms are not necessarily indicative of immunodeficiency.

* Infections of the nervous system with LAV/HTLV-III is also associated with acute, sub-acute or chronic neurologic problems.

C. What is the likelihood that a person infected with the LAV /HTLV-III virus will develop AIDS ?

* Approximately two-thirds of the persons infected with the LAV/HTLV-III virus and followed for at least 5 years have no evidence of ill health. It is not known what risk of disease those individals face beyond five years.

* These individuals have, however, a persistent infection and an unknown proportion of them are infectious to others.

* The remaining one-third develop illness varying in severity from ARC (AIDS-Related Complex) to AIDS.

III. RISK OF TRANSMISSION

A. How is the virus transmitted ?

* LAV/HTLV-III has been isolated from blood, semen, saliva, tears, breast milk and urine and is likely to be isolated from some other body fluids, secretions and excretions.

* Epidemiological evidence has implicated only blood and semen in transmission.

* The etiological agent of AIDS, LAV / HTLV-III, is normally transmitted through :

  - sexual contact (as well as semen donation)

  - exposure to blood and blood products

- from infected mother to child before, during, or shortly after birth.

* Studies of nonsexual household contact of AIDS patients indicate that casual contact with saliva and tears does not apparently result in transmission of infection. Spread of infection to household contacts of infected persons under normal circumstances has not been detected when the household contacts have not been sexual partners or have not been infants of infected mothers.

* Sexual contact has been shown to be the main mode of LAV/HTLV-III transmission. Anal intercourse which frequently results in slight ruptures of the rectum is thought to be a frequent mode of transmission. Through these ruptures, semen containing the virus can enter the blood stream of the uninfected sexual partner.

* However, vaginal intercourse appears capable of transmitting LAV/HTLV-III from an infected man to woman, or from an infected woman to a man.

* The risk of infection with the virus is increased by having multiple sex partners, either homosexual or heterosexual.

* Whether an infected person develops clinical symptoms or not, he/she could still be infectious to others.

* Transmission of LAV / HTLV-III infection through parenteral exposure is the second most common method of acquiring infection. This occurs as a result of the use of blood-contaminated needles or equipment by drug abusers, receipt of infected blood or blood products, or the use of Inadequately sterilized needles or skin-piercing instruments.

* **AT PRESENT, THERE IS NO EVIDENCE THAT THE VIRUS CAN BE TRANSMITTED THROUGH :**

* Casual contact with an infected individual, such as in a family setting, schools or other groups, living or working together.

* Blood sucking insects.

* Food or water, including the preparation or serving of food or beverages.

* Airborne or fecal / oral routes.

-Certification and testing of international travellers is not warranted as a measure to prevent LAV / HTLV - III transmission. Member State are advised by WHO not to consider such measures.

B. **What are the population groups at highest risk of infection ?**

* The highest rates of infection have been observed in the 20-39 year age group.

* In the United States and Western Europe, the great majority of adult cases continue to occur in homosexual and bisexual men, intravenous drug users, persons transfused with cotaminated blood or blood products, and heterosexual contacts of persons with LAV / HTLV - III infection.

* Although it is expected that further cases of AIDS will develop in haemophilia patients and in blood transfusion recipients already infected with the virus, future infections from blood or blood products can now be greatly reduced through the screening of donated blood for the evidence of LAV / HTLV - III antibody as well as the treatment of blood products.

* The risk of trasmission to health care workers appears to be very remote. To date only one confirmed and two possible transmissions to health care personnel have been observed worldwide and these have been through accidental injuries with contaminated neeedles. The precautions normally taken to reduce the potential for infections caused by the hepatitis B virus should be sufficient to also protect health workers against LAV / HTLV - III infection.

IV. PROGNOSIS

A. **Is the immune deficiency status of an AIDS patient irreversible ?**

* At the present time there is no known treatment regimen to restore the immune status of the patient.

B. What is the mortality rate ?

* Based on the surveillance efforts in the U.S.A. as well as Western Europe, cumulative mortality rate among all current and previously identified AIDS cases which fit the strict WHO / CDC case definition is approximately 50%. That is, of all the AIDS cases that have been reported to date to U.S and Western European health authorities, 50% are now deceased. In New York City and San Francisco, AIDS is now the leading killer of single men 25-44 years of age.

* However, for AIDS cases diagnosed 3 years ago, the mortality rate is above 80 %.

* Among those discovered in 1981, the mortality rate approaches 100%.

V. TREATMENT / IMMUNIZATION

A. Are there any effective treatment regimens ?

* To date, no therapy has resulted in restoring the immune function of an AIDS patient.

* At present, the treatment of AIDS patients consists of specific therapies for the oppurtunistic diseases and malignancies involved in each individual case.

B. How promising are treatment regimens currently being evaluated ?

* Major research efforts are under way to identify potentially useful antiviral agents for the prevention or treatment of AIDS and ARC patients.

* Suramin, ribavirin, foscarnet, HPA 23, rifamycins, interferons, and azidothymidine are currently being evaluated ciinically.

* Extensive studies have been performed with suramin and antiviral effects have been observed. However, considerable toxicity has also occured.

* Studies are continuing in Europe and have been initiated in the U.S.A. with HPA 23. Inhibition of viral replication has been observed in these studies, but further studies are required before a conclusive statement can yet be made on efficacy.

* Phase I clinical studies to evaluate toxicity with azidothymidine and ribavirin have been concluded. These drugs apeear relatively safe at the dosage tested and phase -II studies to evaluate efficacy will begin shortly.

* Studies with foscarnet and rifamycins are being initiated in the U.S.A. Small studies in Europe with foscarnet have also been started.

* Interferon alfa studies are continuing in order to determine its role as an antiviral agent.

* Reconstitution of the immune system in AIDS patients is also being attempted and includes :

  - Bone marrow transplantations :

  - Immune enhancers such as INTERLEUKIN - II, INTERFERON, GAMMA, THYMIC HARMONES, and a variety of synthetic chemical substances.

* Passive protection modalities are also being pursued, including the development of monoclonal antibodies and hyperimmune gamma globulin.

* Future studies of combined treatment with antiviral agents and immune modulators are anticipated.

C. IS THERE PROGRESS ON A POSSIBLE VACCINE ?

* Multiple approaches to vaccine development are currently underway

* These include the purification of selected envelope components from disrupted virus and the production of envelope protein, by recombinant DNA technology.

* No attempts are being made to develop live attenuated or whole virus inactivated vaccines because of the hypothetical potential for nucleic acid to integrate into host cell DNA.

* Many difficulties / obstacles are foreseen in this area. Effective vaccines will propably not be available witthin the next few years.

* One potential obstacle is the LAV / HTLV- III virus apparent minor mutations that alter the precise molecular structure of its protein coat.

* With multiple strains of LAV / HTLV- III, a vaccine will prove difficult unless a common antigen is found.

* Vaccination of persons with pre-existing infection is unlikely to be effective.

* Ameliorating or preventing the clinical effects in already infected persons by vaccination is also unlikely.

VI. MORBIDITY / MORTALITY PATTERNS

A. How many cases have been reported thus far ?

* 23,919 cases in 86 Countries have been reported as on 1-05-86.

* The report reflects cases reported voluntarily by countries and cannot thus accurately reflect the incidence of the disease on a worldwide basis.

* The available information reflects a wide spectrum of reporting procedures ranging from regular and recent reports from some countries, to periodic reports from others, and to no reports from yet another group of countries. Many developing countries in Asia, Latin America and Africa are in the intial process of establishing reporting procedures for AIDS.

B. Does WHO feel AIDS should be a notifiable disease ?

* WHO feels that health officials in all coutries should be aware of AIDS and consider the instituion of surveillance programmes to determine the magnitude of the AIDS problem in individual countries.

* For worldwide surveillance, the volunatary participation of Member States in the collection of data on the incidence of AIDS and the rapid transmission of this information to a central source such as WHO would be considered crucial.

* The issue is not whether the disease should be notifiable or not but whether Member States on a worldwide scale truly believe that they can benefit from a global surveillance effort. Making a disease notifiable does not of itself ensure that the disease will be notified.

C. What are the area / countries with the highest reported cases in the World ?

* With some exceptions, developed areas such as the U.S.A. Western Europe, Canada, and Australia have higher reported AIDS cases in relation to their population (rates) than do the developing countries.

* However, many developing countries are in the intial process of establishing reporting systems for AIDS.

* The current situation may, therefore, reflect a reporting artefact and not necessarily the true worldwide distribution of this problem.

D. Why does AIDS seem to be unevenly distributed ?

* The available information reflects a wide spectrum of reporting procedures ranging from regular and recent reports from some countries, to periodic reports from others, and to no reports from yet another group of countries. Many developing countries in Asia, Latin America and Africa are in the initial process of establishing a clinical definition of AIDS applicable to their settings as well as reporting procedures for AIDS.

* As a result it is difficult to determine, at the moment, whether AIDS cases are in fact unevenly distributed.

VII. BLOOD AND BLOOD PRODUCTS

A. What about the safety of blood and blood products ?

* WHO convened a meeting of experts on 14-16 April 1986 to review available information on the safety of blood and blood products in relation to AIDS . It was followed by a consultation which took into consideration previous recommendations, new information, and the many different circumstanses which exist regarding AIDS at the global level.

* Fortunately, effective control measures can reduce markedly the risk of transmitting LAV/HTLV - III infection through blood and blood products. Such measures must be considered in the larger context of national activities toward AIDS prevention.

* Even though tests to detect antibody to the AIDS virus are now available to assist in the elimination of potentially infectious units of blood and plasma, it is important to recognise that information and education remain crucial elements in any AIDS prevention programme and that they continue to be relevant to the safety of blood and blood products.

* The following specific recommendations are to be interpreted in the light of the specific circumstances of different countries, their overall health care needs and priorities, and their present degree of involvement in the AIDS epidemic. Revisions of these recommendations will be needed to reflect evolving technologies as well as future scientific insights.

* The public should be clearly informed that blood donation itself does not incur any risk whatsoever of infecting donors with the AIDS virus.

* Donor education and selection programmes are warranted to eliminate potentially infectious units of blood and plasma from being collected.

* Blood for transfusion and preparation of components should be tested for antibodies to LAV / HTLV - III when the risk of transmitting the virus is significant, and when the benefits of such testing outweigh other important factors in providing blood.

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* Donors should be made aware in advance of their donation that their blood will be tested for the presence of serological markers of virus infection.

* Blood from which plasma derivation are manufactured should be shown to be free of serological markers of LAV / HTLV -III in areas where the virus is prevalent. Specific exceptions might be considered appropriate by national control authorities based on therapeutic benefit and safety of the product.

* Countries which import blood products should consider, whereever feasible, reviewing manufacturing protocols to assess the acceptability of the products taking into consideration these conclusions and recommendations.

* WHO should reference materials and sera for use in evaluating and standardizing laboratory tests.

* WHO should attempt to establish uniform scientific criteria for heat inactivation, chemical treatments, and serological testing of blood products regarding AIDS.

* WHO should review its requirements to take new manufacturing and screening procedures into account.

VIII PREVENTION

A. How can the spread of LAV / HTLV- III infection be prevented among high-risk groups ?

* Communities need to inform their populations about AIDS with special emphasis on educational activities directed towards members of high-risk groups.

* Homosexual / bisexual men as well as intravenous drug users should be informed about relevant measures to reduce the risk for LAV / HTLV- III infection.

* Sexual contacts with persons known or suspected of having AIDS should be avoided.

* Sexual contacts with multiple partners or with persons who have multiple partners should be avoided.

* The risk of LAV / HTLV- III infection is likely to be reduced by the use of condoms.

* Anal intercourse has been shown to further increase the risk of infection for the receptive partner and should be avoided.

* Intravenous drug users should also be informed that the sharing of needles and syringes poses a special risk for LAV / HTLV- III infection.

* Groups at increased risk for LAV / HTLV- III infection should be urged to refrain from donating blood, plasma, body organs, other tissues or semen.

* If they are to be reused, needles, syringes and other instruments which break the skin (e.g. , in circumcision, ear piercing, tattooing, or scarification) must be thoroughly cleaned and disinfected after each use. Disinfection with hypochlorite solutions (diluted household bleach, Eau de Javel), formaldehyde, gluteraldehyde, alchohol or boiling can be considered effective against LAV / HTLV- III virus.

* Toothbrushes, razors or other implements that could become contaminated with blood should not be shared.

B. How can the spread of LAV / HTLV- III infection be prevented from individuals bound to have antibodies to LAV / HTLV- III ?

* Individuals who have been found with the positive LAV / HTLV- III antibody test should be informed that they could pass the disease to others. As a result, they should be counselled to refrain from donating blood, plasma, body organs, other tissues or sperm.

* They should take precautions against exchanging body fluids during sexual activity. The effeciveness of condoms in preventing infection is not proved, but their consistent use may reduce transmission.

* There is a risk of infecting others by sexual intercourse or sharing of needles.

* Tooth brushes, razors, or other implements that could be contaminated should not be shared.

* Women whose sexual partner is antibody-positive are themselves at increased risk of acquiring AIDS.

* Infected women who become pregnant may be more likely to develop AIDS during pregnancy and also may trasmit LAV / HTLV- III infection to their child before, during, or shortly after birth.Infected women should be counselled about these risks and offered contraception if desired.

C. **How can the spread of LAV / HTLV- III infection be prevented when blood and blood products are used in treating patients ?**

* Donor education and selection programmes are warranted to eliminate potentially infectious units of blood and plasma from being collected.

* Blood for transfusion and preparation of components should be tested for antibodies to LAV / HTLV- III when the risk of transmitting the virus is significant, and when the benefits of such testing outweigh other important factors in providing blood.

* Blood from which plasma derivation are manufactured should be shown to be free of serological markers of LAV / HTLV- III in areas where the virus is prevalent. Specific exceptions might be considered appropriate by National Control authorities based on therapeutic benefit and safety of the product.

* Potential donors of organs, sperm , or other human material should be informed about AIDS and groups at increased risks of infection should exclude themselves from donating. Serological testing should be performed before these materials are used.

D. **How can the spread of LAV / HTLV- III infection to hospital staff and / or other health care workers be prevented ?**

* An inadvertent needlestick exposure to LAV / HTLV- III contaminated blood may pose a problem to the health care profession, although based on current studies, LAV / HTLV - III infections appear to be much less transmissible through needlestick injuries than hepatitis B.

* Health care personel should follow recommendations designed to minimize the risk of exposure to parenteral or mucosal (e.g. blood spatter or conjunctiva) contact with potentially infectious materials from patients with AIDS or suspected AIDS.

* Epidemiological studies of needlestick injuries in hospital personnel indicate that over 40 % of the accidents are potentially preventable if recommended precautions are followed when handling used needles or other sharp objects.

* Educational programmes to familiarise health care workers with basic practices in infection control are essential to the prevention of AIDS and other infections.

1X NATIONAL AIDS CONTROL STRATEGY

The strategy for control has been built around the following :

a) It is a fatal disease assuming an epidemic form throughout the world causing widespread concern among medical profession. and public at large, indicating thereby an urgent need for establishing a network of monitoring and surveillance in the country.

b) There is also an urgent need to involve and educate people about the correct facts of the disease and preventive steps.

c) There is also an immediate need for formulation of specific clinical diagnostic criteria in Indian context and for establishment of adequate laboratory and surveillance centres to detect cases and understand epidemiology of the disease.

The WHO has recommended the following courses of action :

1) Inform people about AIDS infection and its mode of transmission to allay inappropriate public concern.

2) Inform health care workers of methods of prevention and control.

3) Assesssment of risks that AIDS poses to its population and establish methods of diagnosis.

4) Undertake regular and periodic serological studies to identify the existence of AIDS infection in high risk group.

5) Discourage high risk group from donating blood, organs, sperm and other human material.

6) Follow up of cases detected and its proper methods of assessment.

7) Develop guidelines for care of the patient and handling of materials in hospitals / laboratories.

Based on the above the following strategy is prepared.

1) Establishment of monitoring and surveillance mechanism to cover the entire nation. Indicate structural and as well as functional components at National and State Level.

2) Identification of high risk group and high risk areas in consultation with State Health Authorities.

3) Development of suitable mechanism for periodical survey among high risk groups through STD clinic / identified surveillance centres and other means.

4) Working out specific guidelines for management of detected cases and their follow up.

5) Specific guidelines for blood bank, blood product manufacturers, professional blood donors, import of blood products, drug de-addiction clinics, dialysis units etc.

6) Training of professionals / para professionals in case detection, management and follow up and building up of expertise in AIDS detection and control in the country.

7) Information, Education and Communication by involving all media and other health education channels.

8) Precautionary guidelines for laboratory staff and health workers and allied professionals.

9) Supporting research studies in the field to generate relevant information in control, prevention and management of AIDS cases.

ESTABLISHMENT OF MONITORING & SURVEILLANCE MECHANISM TO COVER THE ENTIRE COUNTRY

a) Creation / establishment at the National / State level a cell to act as a nodal point for monitoring AIDS in the country. As the situation is of very urgent nature and demanding it may not be possible to go through all formalities for creation of such nodal points. Therefore, the National / State authorities may designate one suitably ranked senior officer in the Directorate as National /State AIDS Officer and he may be given a supporting staff so that he may function effectively. It is expected that the State may create such facilities by the end of June 1986.

b) Once it is established, the concerned officer should be called for three days workshop at National Institute of Communicable diseases / National Institute of Virology under the overall control of I.C.M.R. for training and working out details of the operational mechanism for surveillance and monitoring mechanism in the country / State.

c) Establishment of atleast one surveillance centre in each State to undertake Serological Study for AIDS. Seven centres are already functioning and the remaining will be identified by I.C.M.R. by the end of June, 1986. Once identified concerned officers should be sent for training at the earliest so that the surveillance centre becomes operational early. Each centre subsequently can identify 3 to 5 more sentinel centres in course of time so that all over the country a wide net work of surveillance machinery is established shortly.

d) Serological materials obtained from the high risk groups routinely through STD clinics and special survey should reach the surveillance centres and once cases are identified specific actions should be initiated as per the guidelines evolved.

e) All the surveillance centres so identified should be supplied Test Kits through the centre. As the Test Kits are expensive and as large number of Test Kits may be needed the cost involved will be large. Therefore, the centre may arrange the supply of kits to begin with and the State may share the expenditure later.

It may be added here that the shelf life of the kits is very short. Therefore there is a need to exercise utmost caution in procurement of the kits from abroad. It is suggested that the Government of India through its own institutes / ICMR shall provide training to all category of persons and supply Test Kits to the Surveillance centres. The State may come forward to open up peripheral sentinel surveillance Centres, undertake periodical survey among high risk groups, provide facilities for management and follow up of the detected case as per the guidelines. All the STD Cells may do AIDS counselling work once or twice a week.

f) Any case detected by the surveillance centres should be reconfirmed by atleast two other surveillance / referral centres by Elisa / Western Blot before the case is declared positive.

IDENTIFICATION OF RISK GROUP & RISK AREAS

The epidemiology of the disease is rather inadequately known and it varies widely from place to place. In America, Europe and Australia 70 % of AIDS cases are amongst homosexuals. The disease has also been found amongst I / V or I / M drug abusers, homophiliacs and other patients requiring blood transmissions, multiple heterosexual partners, infants of infected mothers etc. The six cases detected in India are among prostitutes.

The virus has been isolated from blood, sperm, tear, breast milk and urine and saliva. Epidemiological evidence has so far implicated only blood / semen in transmission.

Recent information indicates that AIDS may be a serious public health problem in tropical Africa. There is an equal incidence of male and female among African AIDS and heterosexual contact is the most frequent mode of transmission in Central Africa.

Non-sexual household contacts, and infants of non-infected mothers have been found free from acquiring infection from AIDS patients. It is normally transmitted through sexual intercourse, parentenal exposure to blood / blood products and through infected mothers to child in uterus or during postnatal period. At present there is no epidemiological evidence that the virus can be transmitted through casual contact with an infected individual such as contact in a family setting, school or other groups living or working together, through blood sucking insects, food, water or air or through oral route. In the above context it is, therefore, the high risk groups who should be put immediately under surveillance are :

1. Patient attending STD clinics and their contacts.

2. I / V or I / M drug abusers.

3. Professional blood donors.

4. Homosexual inmates of jail.

5. Vigilance Homes, Remand homes etc.

6. Prostitutes.

7. Call girls.

8. Eunuchs.

9. Hoemophiliacs or other patients requiring repeated blood transmission.

10. Patient attending medical college hospitals with typical syndrome.

The high risk areas are :

1. Tourist spots where foreign visitors frequent viz. Goa, Bombay, Delhi,Varanasi, Trivandrum and Jammu and Kashmir.

2. Vigilance Homes, Remand homes, Red light areas, Jail etc.

DEVELOPMENT OF SUITABLE MECHANISM FOR PERIODICAL SURVEY AMONGST HIGH RISK GROUPS.

The Surveillance Centres shall carry out periodic survey as per the calender of activities drawn for the purpose and the cases so detected should be handed over to the concerned health authorities for proper management and follow up. Periodical meeting of all the surveillance centres should be held to review the latest situation and suggest appropriate measures.

ESTABLISHMENT OF MECHANISM OF MANAGEMENT OF DETECTED CASES AND THEIR FOLLOW UP ETC.

The State health authorities should identify 1 or 2 physicians in each district, train them for proper management of cases and their follow up.

GUIDELINES FOR BLOOD BANKS / BLOOD PRODUCT MANUFACTURERS

Infections due to AIDS can be transmitted by transfusion of whole blood, blood cells, platelets and factor VIII and IX from human plasma.

There is no evidence to date that transmission can occur through other blood products such as albumin, immunoglobulin prepared by conventional colin fractionation for I / M use. Therefore, the following measures are suggested.

1. Donors having high titres of antibodies to hepatitis B virus or cytomegalo virus may be more likely to be members of AIDS risk groups.

2. Popularising voluntary blood donation.

3. Maintenance of confidential records in blood and plasma donation centres.

4. Proper processing of the products.

5. More use of products of small pool donors.

6. Sera from donors of sperm, organs or tissue used for transplantations should be tested for AIDS virus antibody.

7. Drug abuse should be condemned and all drug abusers should be informed about the risk of using nonsterile needle.

8. Avoidance of unnecessary use of injectables medicines, skin piercing for cosmetic or ritualistic purpose.

TRAINING OF PROFESSIONALS / PARA PROFESSIONALS

This is an important area which needs immediate attention. ICMR may arrange for training several personnel in the country and now it has been decided that training could be given at all ICMR referral centres and by the end of June at least one team of trained personnel would be available for each State through the efforts of ICMR. Once Surveillance centres are established the same will take up on a larger scale this training load of para medical workers. It is expected that by the end of July, 1986 enough expertise will be available to reach any part of the country at short notice from within the State.

INFORMATION, EDUCATION AND COMMUNICATION

Education about the modes of transmission of the virus and the various outcome of infection is considered the single most important element in control of the disease. Studies in USA have shown that high risk groups have been prepared to change their life styles and behaviour pattern voluntarily to avoid the more obvious risks of infections.

However, the job is tough and challenging.The mysteries surrounding AIDS have bred a great deal of fear and strong prejudices and people frequently behave unreasonably and strangely towards those who are AIDS infected.

Misunderstanding are, therefore, common over the issue of household contacts, casual contacts etc. The virus has been isolated from many body fluids but till now there is no evidence that any one has been infected through any other medium than that of blood or semen (apart from infants of infected mothers). Further more contact between people like shaking hands, sharing meals, coughing or sneezing, visiting a hair dresser, manicurist, optician, dentist are not involved in AIDS transmission.

Though the casual contact is unimportant in AIDS transmission, its remote possibility cannot be ruled out. People should, therefore, take steps to protect themselves from possible contamination with infected AIDS materials. This means observing high standard of hygiene including washing dishes / hands in hot soapy water.

Therefore, there is an urgent need to tap all avenues of mass media education and communication channel to reach all segments of people with correct information about the disease.

PRECAUTIONARY GUIDELINES FOR LABORATORY STAFF, HEALTH WORKERS ETC.

1. Handle sharp instruments contaminated with AIDS materials carefully to avoid accidental wound.

2. Wearing of gloves, gowns while handling infectious materials like blood,body secretions etc.

3. Thorough washing of hands after handling infectious materials.

4. Disinfection of specimen container or any surface contaminated with blood with powerful disinfectant.

5. Incineration of disposable items and articles soiled with infected material.

6. Compulsory use of disposable needles & their proper disposal.

7. Labelling of blood & other specimens with special warnings.

8. Use of biological safety cabinet and other primary containment devices for various laboratory instruments.

COMMUNITY HEALTH CELL
LIBRARY AND DOCUMENTATION UNIT

9. Proper decontamination of working.

10. Strict prevention of mouth pipetting.

11. Maintenance of a separate room for specimen collections of AIDS patients.

12. Decontamination of animal cages and proper precautions while handling experimental animals.

SUPPORTING RESEARCH STUDIES

This is an important area. ICMR has already constituted a task force on the AIDS. The same task force may suggest a few protocals in key areas of interest.

X. GLOSSARY OF TERMS

Name of Diseases

AIDS _____	Acquired Immunodeficiency Syndrome
ARC _____	AIDS - Related Complex
KS _____	Kaposl's sacroma. A malignancy which usually occurs anywhere on the surface of the skin or in the mouth. Atleast moderately predictive of cellular immunodeficiency and, in turn, AIDS when occuring in persons less than 60 years of age.
LAS _____	Lymphadenopathy Syndrome
OI _____	Oppurtunistic Infection. Severe infections (parasitic, fungal, bacterial or viral) occuring in persons with cell-mediated immune deficiency. Milder infections with these organisms do not suggest immune deficiency.

Name of Causative Agent

ARV _____	AIDS Related Virus
HTLV-III_____	Human T cell Lymphotropic Virus type III
LAV _____	Lymphadenopathy Associated Virus or Lymphadenopathy AIDS Virus (L.Montagnier)
LAV / HTLV-III _____	The most widely used name for the causative agent of AIDS.
RV _____	Retrovirus, Virus belonging to retroviridae (e.g., HTLV-I, HTLV-II, LAV / HTLV-III, etc.)

BLOOD PRODUCTS

Factor VIII	_ _ _ _ _ _ _ _ _ _ _ _	Antihaemophiliac factor. Deficiency of this factor, when transmitted as a sex-linked recessive trait, causes classical haemophilia (haemophilia A).
Factor IX	_ _ _ _ _ _ _ _ _ _ _ _	Plasma thromboplastin component. Deficiency of this factor results in a haemorrohagic syndrome called haemophilia B which is similar to classical haemophilia.

Name of Laboratory Tests

CRIP	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Competitive Radio Immuno Precipitation
ELISA	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Enzyme Linked Immuno Sorbent Assay
EM	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Electron Microscopy
IF	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Immuno Fluorescence
RTA	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Reverse Transcriptase Assay
SPRIA	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Solid Phase Radio Immuno Assay
WB	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Western Blot Method

Other

Lymphoid Cell	_ _ _ _ _ _ _ _ _ _	A mononuclear cell ultimately concerned with humoral or cellular immunological reactivity
B-cells	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _	B-lymphocytes. These cells mature as plasma cells that synthesize humoral antibody.
T-cells	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _	T-Lymphocytes that suppress or assist the stimulation of antibody production in B-lymphocytes in the presence of antegen. They are thought to have a long life span and to be responsible for cell-mediated immunity and immunological memory.

XI.SURVEILLANCECENTRES

CITY	SCIENTISTS/INSTITUTION	TERRITORY
Chandigarh	PGIMER*	Punjab,Haryanaand Chandigarh
Srinagar	Sher-E-KashmirInstitute*	JammuandKashmir
Delhi	Dept.ofClinical Immunology*	Delhi
	Deptt.ofMicrobiology*	A.I.I.M.S
	N.I.C.D*	
Simla	MedicalCollege	HimachalPradesh
Lucknow	K.G.MedicalCollege	UttarPradesh
Jaipur	S.M.S.MedicalCollege	Rajasthan
Patna	R.M.R.I.*	Bihar
Calcutta	N.I.C.E.D.*	WestBengal,Sikkim, Andaman&NicobarIslands
-do-	SchoolofTropicalMedicine*	-do-
Gauhati	MedicalCollege	Assam
Manipur	RegionalMedicalCollege	Manipur,Tripura, Megalaya,Nagaland, ArunachalPradesh, Mizoram.
Bhubaneshwar	R.M.R.C*	Orissa
Cuttack	CuttackMedicalCollege	-do-
Jabalpur	R.M.R.C	MadhyaPradesh
Bhopal	GandhiMedicalCollege	MadhyaPradesh
Vadodara	MedicalCollege	Gujarath
Bombay	SethG.S.MedicalCollege	Maharashtra
Pune	N.I.V.*	Maharashtra
Nagpur	NagpurMedicalCollege	Maharashtra
Panaji	GoaMedicalCollege	Goa,Daman,Diu, DadraNagarHaveli.
Trivandrum	MedicalCollege	KeralaState Laccadives
Madras	MadrasMedicalCollege	Tamilnadu
Vellore	C.M.C.	Tamilnadu
Pondicherry	J.I.P.M.E.R.	Pondicherry,Mahe, Karaikal
Hyderabad	InstituteofPreventive Medicine	AndhraPradesh
Bangalore	MedicalCollege/Kidwai MemorialCentre/NIMHANS	Karnataka

*AlreadyEstablished.

NATIONAL AIDS CONTROL STRATEGY

DGHS CELL

I. C. M. R.
S&T CELL

a. Lab Diagnosis
b. Research
c. Training

REFERRAL CENTRE

AIIMS
CMC
NIV
NICD

a. Confirmation of lab diagnosis
b. Working out diagnostic criteria
c. Advanced training
d. Research

SURVEILLANCE CENTRE

One in each state

a. Initial lab diagnosis
b. Periodic survey
c. Training
d. Research

Identifying high risk areas & high risk group

Working out guidelines for periodical Survey

Guidelines for case management and follow-up

4.

5.

1. Monitoring of AIDS & co-ordination at the national level
2. Involvement of mass media and all health educational channel to educate people
6. Guidelines in respect of blood bank, blood products, sterilisation of syringes, drug de-addiction clinics
7. To supply requisite test kits, equipments to surveillance/referral centres through NICD/ICMR
8. To offer assistance to State Govt. as & when required

STATE D.H.S. CELL

Monitoring & co-ordination at state level

Identification of high risk group & high risk areas

Collection & transportation of clinical material through STD clinics/ survey team

Management of detected cases & follow up through hospitals

Implementation of guidelines for blood bank, blood products sterilisation, drug de-addiction clinics

Procurement of test kits & its supply

Involvement of mass media and other health education channels to educate people

Establishment of Sentinal Centres to be hooked up with surveillance centres

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